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10/723,789	11/26/2003	Charles Cameron Brackett	134689IT/YOD GEMS:0238	9064
7590 Patrick S. Yoder FLETCHER YODER P.O. Box 692289 Houston, TX 77269-2289			EXAMINER SAMPSON, BRUCE	
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SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/723,789

Applicant(s)

BRACKETT ET AL.

Examiner

Bruce Sampson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 45 -50 are rejected under 35 U.S.C. 101 because the claimed invention is directed to not-statutory subject matter.

Regarding claim 45, the image processing method must be implemented on a computer readable medium and it must contain computer executable instructions. Otherwise, the instructions cannot be executed.

Regarding claim 46, the image processing method must be implemented on a computer readable medium and it must contain computer executable instructions. Otherwise, the instructions cannot be executed.

Regarding claim 47, the image processing method must be implemented on a computer readable medium and it must contain computer executable instructions. Otherwise, the instructions cannot be executed.

Regarding claim 48, the image processing method must be implemented on a computer readable medium and it must contain computer executable instructions. Otherwise, the instructions cannot be executed.

Regarding claim 49, the image processing method must be implemented on a computer readable medium and it must contain computer executable instructions. Otherwise, the instructions cannot be executed.

Regarding claim 50, the image processing method must be implemented on a computer readable medium and it must contain computer executable instructions. Otherwise, the instructions cannot be executed.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 6, 8, 10, 11, 13, 15, 18, 19, 20, 21, 22, 24, 39, 42, 43, 44, 45, 46, 48, 49 and 50 rejected under 35 U.S.C. 102(b) as being anticipated Gur I (US 5627907).

Regarding claims 1, 2, 6, 8, 10, 11, 13, 15, 18, 19, 20, 21, 22, 24, 39, 42, 43, 44, 45, 46, 48, 49 and 50, Gur I discloses a method for registering images, comprising: segmenting a feature of interest [(paragraph 17 line 1). segmenting a corresponding feature of interest in a second image (Gur I, paragraph 18 lines 1-2); registering the first image with the second image by aligning the feature of interest with the corresponding feature of interest(Gur I, Paragraph 18, especially lines 6-7); and storing image data corresponding to registration. The boundary information would have to be stored

because it is needed in later processing. The longest axis must be computed for example (paragraph 33). Since the boundary is registered and stored two points on the boundary are registered and stored as required in claims 1, 2, 6, 8, 10, 11, 13, 15, 18, 19, 20, 21, 22, 39, 42, 43, 44, 45, 46, 48, 49 and 50.

In Gur I's method, the boundary is detected. Then the images are aligned (Gur I, Fig 4A S3 and S4). Thus, a point on the boundary is used to align two images and subtract them as required in claim 13, 18, 19 and 44. Also a second point on the boundary would be needed to align two images and subtract them as required in claims 21, 22, 24 and 50 (Gur I, Fig 4A S3 and S4). Then the feature of interest is framed and mapped back to the original image. (Gur I, Fig 4A S7). The boundary information would have to be stored because it is needed in later processing. The longest axis must be computed for example (paragraph 33). Since the boundary is registered and stored two points on the boundary are registered and stored as required in claims 13, 18, 19, 21, 22, 24, 44 and 50.

Notice the first reference point and the second reference point are location markers for the registration since they are on the boundary as required in claim 24.

Gur I displays the suspicious regions (Gur I paragraph 72, Gur I fig 8 step s828 combined) as required in claims 2, 11, 43, 44, 46, 49 and 50.

The feature of interest and the corresponding feature of interest are an anomaly as required in claim 15.

The segmentation step is automated as required in claim 18. (Gur I, paragraph 188)

The registration step is automated as required in claim 19 [(Gur I, abstract, lines 3-8) If abnormal regions are detected and displayed using the computer, they are registered)]

The process of segmentation fixes the size of the abnormality (i.e. the feature of interest) in the first and second regions. One of ways listed for identifying the abnormality is to determine it's size (Gur I, paragraph 21). Thus, Gur I taught a procedure for sizing the abnormality (i.e. the feature of interest), as required in Claims 21 and 22.

Notice that one or more computer aided techniques are used to identify and size the feature of interest and the corresponding feature of interest as required in claim 22. [The segmentation step was automated (Gur I, paragraph 188). The identification step was automated (Gur I, abstract lines 4-5)].

Regarding Claims 39, Gur I lists 6 means for identifying a feature of interest. (Gur I, paragraph 28).

5. Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosinko (EP 1057455A2), hereafter referred to as Rosinko.

Regarding claim 1, Rosinko discloses a method for aligning images, comprising: identifying a feature of interest in a first image [(P11 line 43 and P11 line 50-53 and p12 lines 9-11 combined). The working image is the first image] identifying a corresponding feature of interest in a second image[(P11 line 43 and P11 line 50-53 and p12 lines 9-11 combined), the live fluoro image is the second image]; registering the feature of interest within the first image with the corresponding feature of interest within the second image; and storing registration data corresponding to registration. [(P11 line 43 and P11 line 50-53 combined and p12 lines 9-11) The working image is the former image. Overlaying the working image onto the live fluoro image in such a way that the radiopaque markers overlap amounts to registering the features of interest.]

The registration data is displayed as an overlay of the first image and second image in stack mode as required in claims 2 and 4 [(Fig 1 # 106 and # 116 and p12 lines 9-11)].

6. Claims 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gihuijs, et. al. (US 6317617) hereafter referred to as Gihuijs.

Regarding Claims 6 and 9, Gihuijs discloses a method for registering images, comprising: segmenting a feature of interest in a first image (paragraph 10 and paragraph 11, lines 7-9); segmenting a corresponding feature of interest in a second image(paragraph 10 and paragraph 11, lines 7-9); registering the first image with the second image by aligning the feature of interest with the corresponding feature of interest [(paragraph 30 lines 1-3 and paragraph 31, lines 1-3) If the images are

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displayed, they have to be registered]; and storing image data corresponding to registration. Note: first image and second image are acquired by different modalities (paragraph 31 lines 1-3).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 3, 5, 7, 12, 14, ^{1,}41 and 47 rejected under 35 U.S.C. 103(a) as being unpatentable over Gur I (US 5627907) in view of Roehrig et. al. (US 6075879) hereafter referred to as Roehrig II. Notice that Roehrig III (application no 09/990508)

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incorporates both Gur I (Paragraph 6 line 9) and Roehrig II (paragraph 6 line 14 by reference.

Regarding claims 3, 5, 7, 12, 14, 17, 41, and 47, Gur I teaches all of the limitations of claims 1, 2, 6, 11, 13, 19, 20, 21, 44, 45 and 46. Gur I fails to teach a method where the first image and the second image are acquired in different temporal settings. Roehrig II compares a suspicious region with a suspicious region from 12 months ago (Roehrig II, Col 13 line 62). Therefore, it would have been obvious to one of ordinary skill at the time of the invention to compare the suspicious regions from different temporal settings. They would have been motivated to do this in order to monitor the behavior of the abnormality over time.

Roehrig II also include a method of displaying the registration data comprises displaying a composite image of the first image and the second image as required in claims 3, 5, 12, 14, 41 and 47. (Col 5, Lines 50-56 and Col 5 lines 29-39).

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gur I (US 5627907), hereafter referred to as Gur I, in view of Gur II(US6067372).

As shown above, Gur I teaches all of the limitations of claim 13 except having the reference point at the middle of the feature of interest. Regarding Claim 16, Gur II teaches a method of wherein the first reference point is the middle of the feature of interest; and the second reference point is the middle of the corresponding feature of interest. (Gur II, paragraph 25, lines 3-4). Therefore it would have been obvious at the time of the invention to modify Gur I by using the middle of the feature of interest as the

reference point. They would have been motivated to do so because Gur II's method was published later than Gur I's method. Therefore, it would appear that Gur thought the method described in Gur II was better. Note that Gur II incorporates Gur I by reference.

11. Claim 23, 29, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gur et.al. (US 6067372), hereafter referred to as Gur I. in view of Giger et al (US 5133020) hereafter referred to as Giger. (Notice Roehrig et. al. (Application No 09/990508), hereafter referred to as Roehrig III incorporates both Gur I (Roehrig III, paragraph 6 line 9) and Giger (paragraph 5 line 5) by reference.)

Regarding claim 23, Gur I teaches all of the limitations of claims 21. Gur I fails to teach a method, wherein the feature of interest and the corresponding feature of interest are manually identified. Giger teaches a method wherein the feature of interest and the corresponding feature of interest are manually identified. (Giger, Paragraph 25 lines 7 - 9). Therefore it would have been obvious to one of ordinary skill at the time of the invention to use a method wherein the feature of interest and the corresponding feature of interest are manually identified. They would be motivated to do so, since no automated detection scheme is perfect. Thus, it is important to give doctors the ability to manually correct the results.

Regarding claims 29 and 30, Gur I teaches all of the limitations of claim 21. Gur I fails to explicitly teach a method, comprising accessing the registration data to compare the first image with the second image. Giger teaches a method further comprising

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accessing the registration data to compare the first image with the second image.

(Giger, paragraph 4 lines 3-4 and paragraph 4 lines 8-12 and Paragraph 3 lines 9 and 10). In order to compare images of the abnormality separated by a several month interval, registration data would have to be accessed. Regarding claim 30 Giger uses the registration data to compare the abnormal regions, which are the regions of interest.

Regarding claim 31, Gur I and Giger teach all of the limitations of claims 21 and 30.

Giger displays a composite image of the suspected lesion. (paragraph 12, fig. 8, paragraph 3 lines 9-10 and paragraph 2 line 7).

12. Claim 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gur I (US 5627907) hereafter referred to as Gur I, in view of Moshfeghi (US 5633951), and in further view of Giger (US 5133020).

Regarding claim 25 – 28, Gur I teaches all of the limitations of claims 21 and 24. Gur I fails to explicitly teach registration of the abnormality using various transformations such as warping. Pertaining to the same field of endeavor of registering medical images, Moshfeghi uses warping to registers a general regions. (Section 2, contour extraction). Moshfeghi's method first requires boundary extraction. If only one slice is used rather than a several slices (Moshfeghi, Col 7 line 15), the method becomes 2d rather than 3d. The boundary of the abnormality will be a 1 dimensional curve and the abnormality will be a 2 dimensional feature of interest. Gur I has already extracted an appropriate boundary [(Gur I, paragraph 18, line 9) the regions are framed], so there is no need to apply Moshfeghi's contour extraction algorithm(Moshfeghi, Section 2. contour

extraction). If Moshfeghi's algorithm is applied to a rigid body, it will register the rigid body as required in claims 25 and 26. (Col 1 lines 24-47). If a warped registration is required, in order to register a warped abnormality, it can do an elastic registration (Fig 2 #38 and Fig 2 # 40) as required in claim 28. In an intermediate step each point on the 2d abnormality would be registered with a triangle on the other 2d abnormality. Since these abnormalities are planar in the 2d modification of Moshfeghi's algorithm, this intermediate step would amount to rigid body registration as required in the first part of claim 28. Then later in a warped registration is performed, as the steps are iterated. (Col 11, lines 22-25.). Moshfeghi uses his algorithm to register medical images. Giger compares mammogram abnormalities at different times (paragraph 3 lines 9-10). Giger realizes the importance of registering mammogram images using warping (paragraph 4, lines 7-12). Therefore, it would have been obvious to one of ordinary skill at the time of the invention to register the abnormalities using with respect to translation, rotation and/or elasticity and warping. They would have been motivated to do so they could monitor the behavior of the abnormality over time.

13. Claims 32, 35, 36, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gur I (US 5627907) in view of Giger et al (US 5133020) hereafter referred to as Giger.

Gur I teaches a system for registering images comprising: one or more imaging systems for acquiring (Fig. 1 # 1) and storing images (Gur I, paragraph 4); a first interface for reviewing (Gur I, paragraph 72) and processing (abstract lines 4-9), a storage for storing image registration data; and wherein registration of the images is

based on alignment of corresponding features of interest in the images. However Gur I fails to explicitly teach an interface for manually registering or accessing the images. In Giger's method, the doctor can manually register (Giger, paragraph 25, lines 6-9) or access (paragraph 42 lines 2 -3) images through a first interface. Therefore, it would have been obvious for one of ordinary skill to use a method where doctors can manually register the images. They would have been motivated to do so, because some doctors would distrust a fully automated detection algorithm. Such an algorithm could be a liability risk if it did not have a 100% success rate. Having a manual registration option would make the detection algorithm more sellable.

The system includes analog to digital device or scanner (Gur I, paragraph 7) for converting analog film images to digital images as required in claim 35.

The images are digital images and digitally-acquired images (Gur I, Fig 1 # 1) as required in claim 36.

The images are digitized images and scanned images as required in claim 37
[(Gur I, paragraph 7) scanned images are digital images.]

Gur I teaches an imaging systems are at least one of a conventional X-ray imaging system, a digital X-ray imaging system, a CT imaging system, and a MR imaging system as required in claim 38. [(Fig 1 # 1) Digital xrays are used]

14. Claims 33, 40 and 41 are rejected are rejected under 35 U.S.C. 103(a) as being unpatentable over Gur I (US 5627907) in view of Giger et al (US 5133020) hereafter referred to as Giger and in further view of Roehrig II et. al. (US 6075879) hereafter

referred to as Roehrig II. (Note that Roehrig III(application no 09/990508) incorporates Gur I (Roehrig III, paragraph 6 line 9),Roehrig II (Roehrig III, paragraph 6 line 14) and Giger (paragraph 5 line 5) by reference.)

Regarding claim 33, 40 and 41, Gur I and Giger teaches all of the limitations of claims 32 and 39. Gur I fails to teach the use of a second displaying device. Roehrig II includes a method of displaying the registration data comprises displaying a composite image of the first image and the second image as required in claim 33, 40, and 41. (Col 5, Lines 50-56 and Col 5 lines 29-39). The following also pertains to claim 33. It would be obvious to one of ordinary skill at the time of the invention to modify Gur I and include a second display device. They would be motivated to do this so that the radiologist could compare the original image with the image highlighting the abnormality. Although Roehrig II does not explicitly say his backlighting station can also view registered images, it would be obvious to one of ordinary skill at the time of the invention to give it that capability. The backlighting station can view mammograms. They would be motivated to give the backlighting station the ability to view registered information, so that the doctor would not have to always turn on the display device.

15. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gur I in view of Giger et al (US 5133020) hereafter referred to as Giger and in further view of Roehrig et. al. (US 6075879) hereafter referred to as Roehrig II and In still further view of Roehrig (Application No 09/990508) hereafter referred to as Roehrig III.

Regarding claim 34, Gur I, Giger and Roehrig II and teaches all of the limitations of claims 32 and 33. Roehrig II teaches a system that has all of the elements of a

PACS workstation. A PACS workstation has a picture archive(Roehrig II has on Col 5, Lines 50-56 and Col 5 lines 29-39) and communication system [various device are connected together) and a computer network for digitized radiologic images(Roehrig II has on Col 5, Lines 50-56 and Col 5 lines 29-39) and reports. Roehrig III considers the option of combining the display panel 308 and the wet reader viewer 306. (Roehrig III, paragraph 35). Thus, it would be obvious to combine all of the elements of the PACS workstation onto one interface. They would have been motivated to do that so that the system could be more compact. (Note that Roehrig III(application no 09/990508) incorporates Gur I (Roehrig III, paragraph 6 line 9), Roehrig II (Roehrig III, paragraph 6 line 14) and Giger (paragraph 5 line 5) by reference.)

16. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosinko et. al. (US 6075879) hereafter referred to as Rosinko in view of the article "Improved Localization of Coronary Stents Using Layer Decomposition."

Regarding Claim 3, Rosinko teaches all of the limitation set forth in claims 1 and 2. Rosinko can also display video images (Fig 1 # 106 and 116, p7 lines 39-50). According to (R Close, Methods and Materials, paragraph 1 lines 1-4), It is standard to view a sequence of Cine x-ray images during current interventional coronary procedures. Therefore equipment is available for displaying a Cine X-ray image sequences. Thus, it would be obvious to one of ordinary skill to have displaying the registration data comprise displaying a cine serial view of the first image and the second image as required in claim 3. They would be motivated to do so so that the doctor could see the catheter while positioning it.

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Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:


US 54900516 teaches a method and system to enhance medical signals for real-time analysis and high-resolution display. Robert Close et. al discusses a method of improved image guidance of coronary stent deployment. John C. Russ "The Image Processing Handbook" discusses image processing methods. US 4683377 discloses a "Subtraction processing method and apparatus for radiation images".

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Sampson whose telephone number is 571-272-3018. The examiner can normally be reached on Monday-Friday (1st Friday off) 7:30-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Kelley can be reached on 571-272-7331. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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